

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Tracee Eidenschink
Application No.:	10/663641
Filed:	September 17, 2003
For:	BALLOON ASSEMBLY WITH A TORQUE
Examiner:	Catherine Witczak
Group Art Unit:	3767

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Alexandria, VA 22313-1450

Docket No.: S63.2B-11019-US01

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application for which claims 1, 2, 4-33 and 35-52 were finally rejected in the office action dated March 21, 2008.

Claims 1, 2, 4-33 and 35-52 are pending in the application.

A Notice of Appeal was filed in this case on July 2, 2008. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-0350 for any other fees which may be due with this appeal.

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(i) Real Party in Interest

The application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 1, 2, 4-33 and 35-52 are pending in the application and have been twice or finally rejected. Claims 3 and 34 are canceled.

(iv) Status of Amendments

All amendments have been entered to date. A Notice of Appeal was filed on July 2, 2008.

(v) Summary of Claimed Subject Matter

A summary of representative independent claims as required by 37 C.F.R. §41.37(c)(1)(v) and any dependent claims argued separately and a non-limiting listing of locations where support may be found [bracketed citations] referring to the specification by page and line number, and to any drawing, is provided as follows:

Independent claim 1 is directed to an embodiment of an expandable medical balloon having a first unexpanded state, an expanded state and a second unexpanded state, said balloon is mounted on an inner shaft of a catheter assembly. The inner shaft has a torque in the first unexpanded state of the balloon. The balloon has a torque in the first unexpanded state of the balloon and has a torque in the second unexpanded state of the balloon. [page 2, lines 24-34 to page 3, lines 1-27, page 4, lines 22-34 and page 5, lines 1-2, claims 1 and 4 as filed]

Independent claim 22 is directed to an embodiment of a balloon catheter having an expandable member formed according to a method including providing an inner shaft having a distal end and a proximal end, providing a balloon member having a distal end and a proximal end, mounting the balloon member on the inner shaft and applying a torque to the inner shaft such that a torque is applied to said balloon member. [page 2, lines 24-28; page 8, lines 11-16; claim 22 as filed]

Independent claim 33 is directed to a method of providing an expandable member of a balloon catheter with improved rewrap including providing an inner shaft having a distal end and a proximal end, providing a balloon member having a distal end and a proximal end and a first unexpanded state, an expanded state and a second unexpanded state, mounting the balloon member on the inner shaft and applying a torque to the inner shaft resulting in application of a torque to the balloon member. The torque is applied so that the inner shaft has

the torque when the balloon member is in a first unexpanded state. [page 2, lines 24-35 and page 3, lines 1-2; page 8, lines 11-31; claim 33 as filed]

Independent claim 52 is directed to an embodiment of an expandable medical balloon having a proximal waist portion, a proximal cone portion, a body, a distal cone portion and a distal waist portion. The balloon is secured to an inner catheter shaft at the distal waist portion and secured to an outer shaft at the proximal waist portion. The balloon has a first unexpanded state and a second unexpanded state. The balloon has a torque in the first unexpanded state and in the second unexpanded state. [page 2, lines 24-35 and page 3, lines 1-2; page 4, lines 31-34 and page 5, lines 1-11]

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the Examiner erred in rejecting claims 1, 2, 4-8, 10-33, and 35-52 under 35 U.S.C. §102(b) as being anticipated by Hanson (US 4,346,698).

II. Whether the Examiner erred in rejecting claim 9 under 35 U.S.C. §103(a) as being obvious over Hanson in view of Kletschlka (US 6,443,926).

(vii) Argument

A. Brief Summary

I. The Examiner erred in rejecting claims 1, 2, 4-8, 10-33, and 35-52 under 35 U.S.C. §102(b) as being anticipated by Hanson (US 4,346,698).

II. The Examiner erred in rejecting claim 9 under 35 U.S.C. §103(a) as being obvious over Hanson in view of Kletschlka (US 6,443,926).

B. Detailed Argument

I. The Examiner erred in rejecting claims 1, 2, 4-8, 10-33, and 35-52 under 35 U.S.C. §102(b) as being anticipated by Hanson (US 4,346,698).

A. Claims 1, 2, 4-8, 10-33 and 35.

Applicants traverse the rejection.

Independent claim 1 of the present application is directed to an expandable medical balloon having first unexpanded state, an expanded state and a second unexpanded state, the balloon is mounted on an inner shaft of a catheter assembly, *the inner shaft having a torque in the first unexpanded state of said balloon*, the balloon having a torque in the first unexpanded state and having a torque in the second unexpanded state.

Independent claim 22 which is a product by process claim also recites the limitation of “the inner shaft having a torque in the first unexpanded state of the balloon” as does independent claim 33 which is directed to a method of providing an expandable member of a balloon catheter with improved rewrap. Other features are recited in claims 22 and 33.

It was asserted in the Final Office Action mailed 3/21/2008, that “Hanson discloses in Figures 2, 7, and 8 a balloon comprising a torque having a first unexpanded state (Figure 2), an

unexpanded state (Figure 7), and a second unexpanded state (Figure 8); the balloon being mounted on an inner shaft (22); and an outer shaft (66).” Final Office Action, 3/21/2008, page 2, Claim Rejections – 35 U.S.C. § 102.

In order for a reference to anticipate, each and every element of the claimed invention must be disclosed by that single reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP 2131.

Hanson fails to disclose that the inner shaft (22) has a torque as recited in Applicants’ claims 1, 22 and 33. In fact, Hanson discloses the opposite:

In accordance with the invention, the provision of the thin support wire 50 rotatably disposed in the gas supply tube permits the support wire to be rotated or swiveled relative to the gas supply tube, thereby permitting the balloon to be easily and compactly twisted about the support wire. This results in the twisted balloon having a smaller cross-sectional area which approaches that of tip 32 and gas supply tube 22. Thus, the overall cross-sectional area of catheter 20 may be reduced for insertion into smaller incisions. Additionally, the torque applied to twist the balloon during wrapping thereof is not imparted to the gas supply tube thereby preventing stress to and damage of the gas supply tube.

Hanson, US 4346698, col. 5, lines 7-20 (emphasis added)

Thus, because Hanson does not disclose an inner shaft having a torque as recited in Applicants’ claim 1, the reference fails to disclose each and every element of the claim as required to sustain an anticipation rejection under 35 U.S.C. §102(b).

It was further asserted in the Advisory Action that:

Applicants arguments do not overcome the prior art of record. Applicant argues that Hanson does not disclose the inner shaft having a torque. Examiner disagrees. Hanson discloses the inner shaft as having a torque of 0 - which the Examiner considers to read on the Applicant’s claimed invention.

Advisory Action, 6/11/2008, item no. 11

This analysis is flawed. Torqueless is not “a torque”. There is no ambiguity in the claim language. If there were any doubt as to whether or not Applicants intended the term

“having a torque” to encompass “a torque of 0” or no torque, as suggested in the Advisory Action, such doubt can be quickly resolved in light of the specification because it is clearly disclosed that the torque that is applied to the balloon and the inner shaft releases in use, thereby making it clear that the recitation of “having a torque” does not include a torque value of zero. See the specification, page 2, lines 24-34.

While Applicants submit that there is not any doubt as to the meaning of the term “having a torque” as recited in claims 1, 22 and 33, any dispute as to the meaning of the term must first be resolved first using the specification as the source of interpretation:

This court ascertains the meaning of a disputed term by looking to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 [72 USPQ2d 1001] (Fed. Cir. 2004)). “Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence” *Id.* Phillips teaches that these sources should be accorded relative weights in the order listed, with the words of the claims themselves being the most relevant. *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 86 USPQ2D 1225, 1232 (Fed. Cir. 2008).

The fact that the specification clearly states that the torque in both the balloon and the inner shaft is “released” during use, (as discussed on page 2, lines 24-34 as well as on page 3, lines 14-27) resolves any dispute as to whether the recitation of the “inner shaft having a torque” as recited in independent claims 1, 22 and 33, includes a torque value of zero as asserted in the Advisory Action. Clearly, such recitation does not include a torque value of zero, and Hanson’s non-torqued catheter shaft does not anticipate Applicants’ claims 1, 22 and 33.

Claims 2, 4-8 and 10-21 depend from claim 1 and are not anticipated by Hanson for at least the reasons that claim 1 is not anticipated by Hanson.

B. Independent Claim 52

Independent claim 52 is directed to an expandable medical balloon secured to an inner catheter shaft at its distal waist portion and secured to an outer shaft at its proximal waist portion. The balloon has first and second unexpanded states and has a torque in both

The second unexpanded state recited in claim 52, refers to the unexpanded state when the balloon is deflated and it is again torqued, as if it has a “memory” of the original torque, and the torque in the inner is released. This results in better rewrap of the balloon member after an initial inflation. The memory remains even if the balloon is inflated and deflated more than once. See page 2, lines 24-34 and page 3, lines 1-2.

Applicants submit that Hanson also fails to disclose that the balloon re-torques after deflation. In fact, Applicants submit that Hanson discloses the opposite. This is apparent from the statements found at col. 5, lines 48-49: “The sheath also prevents the balloon from unwinding. . . .In addition to locking the balloon in its twisted configuration, the sheath is smooth-walled and, as mentioned, is made of low friction material to facilitate insertion of the catheter.” This disclosure would be understood as indicating that the balloon does not have a memory of the twist, but rather, the twist is no longer present once the sheath is removed. In contrast, Applicants’ balloon will retorque when deflated. See page 8, lines 24-31.

Claim 52 is also not anticipated by Hanson.

II. The Examiner Erred in Rejecting Claim 9 under 35 U.S.C. §103(a) as being obvious over Hanson in view of Kletschlka (US 6,443,926).

It was asserted in the Final Office Action mailed 3/21/2008, that “Hanson et al.

disclose the claimed invention except for the device comprising a stent. Kletschlka disclose in column 8, lines 1-4 that it is known to use a stent in this type of medical device.” Final Office Action, pp. 2-3.

Applicants disagree.

Claim 9 depends from claim 1.

As discussed above, Hanson fails to disclose that the inner catheter shaft has a torque, and Applicants’ recitation in independent claim 1 of the “inner shaft having a torque” clearly does not include a torque value of zero as suggested in the Advisory Action.

Combining a stent as disclosed by Kletschlka fails to render claim 1 obvious because the combination fails to disclose or suggest the element of an inner catheter shaft with a torque as recited in claim 1.

Claim 9 is not obvious over Hanson in view of Kletschlka for at least the reasons that claim 1 is not obvious.

CONCLUSION

For at least the reasons discussed above, claims 1, 2, 4-8, 9-33 and 35-52 are patentably distinct over the art of record.

Reversal of the rejection of claims 1, 2, 4-8, 10-33, and 35-52 under 35 U.S.C. §102(b) as being anticipated by Hanson (US 4,346,698) is respectfully requested.

Reversal of the rejection of claim 9 under 35 U.S.C. §103(a) as being obvious over Hanson as modified by Kletschlka (US 6,443,926) is respectfully requested.

Respectfully submitted,

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viii. Claims appendix

1. An expandable medical balloon having first unexpanded state, an expanded state and a second unexpanded state, said balloon is mounted on an inner shaft of a catheter assembly, said inner shaft having a torque in the first unexpanded state of said balloon, said balloon having a torque in the first unexpanded state and having a torque in the second unexpanded state.
2. The medical balloon of claim 1 further in combination with a catheter assembly said inner shaft having a proximal end and a distal end, said balloon is secured to said inner shaft at said distal end of said inner shaft.
4. The medical balloon of claim 3 wherein said inner shaft has a torque in said second unexpanded state of said medical balloon.
5. The medical balloon of claim 1 wherein the torque releases in said expanded state of said medical balloon.
6. The medical balloon of claim 5 wherein the torque remains in said inner shaft during said expanded state of said medical balloon.
7. The medical balloon of claim 6 wherein said torque in said inner shaft releases when said medical balloon is in said second unexpanded state.
8. The medical balloon of claim 1 in combination with a catheter assembly.
9. The medical balloon of claim 8 further in combination with a stent.
10. The medical balloon of claim 2, said catheter assembly further comprises an outer shaft having a proximal end and a distal end.
11. The medical balloon of claim 10, said inner shaft is tacked to said outer shaft at said proximal end of said outer shaft.
12. The medical balloon of claim 1, said medical balloon rotated about the y-axis at an angle of

about 30° from the y-axis or less in said first unexpanded state.

13. The medical balloon of claim 1, said medical balloon rotated about the y-axis at an angle of about 30° to about 90° from the y-axis in said first unexpanded state.

14. The medical balloon of claim 1, said medical balloon is rotated at an angle of about 30° to about 360° from the y-axis in said first unexpanded state.

15. The medical balloon of claim 1, said medical balloon comprising at least one member selected from the group consisting of thermoplastic polymers, thermosetting polymers or mixtures thereof.

16. The medical balloon of claim 1, said medical balloon comprising at least one material selected from the group consisting of elastomeric polymers, non-elastomeric polymers and mixtures thereof.

17. The medical balloon of claim 1, said medical balloon comprising at least one member comprises at least one material which is a thermoplastic block copolymer.

18. The medical balloon of claim 1, said medical balloon comprising at least one polymer selected from the group consisting of polyolefins, polyesters, polyethers, polyamides, polyimides, polyphenylene sulfides, polyphenylene oxides, polyurethanes, polycarbonates, silicones, styrenic polymers, copolymers thereof, and mixtures thereof.

19. The medical balloon of claim 1, said medical balloon in a folded configuration.

20. The medical balloon of claim 19, said medical balloon in a folded configuration having two or more wings.

21. The medical balloon of claim 1, said medical balloon in a folded configuration having three or more wings.

22. A balloon catheter having an expandable member formed according to a method comprising the steps of:

- a) providing an inner shaft having a distal end and a proximal end;
- b) providing a balloon member having a distal end and a proximal end, said balloon member having a first unexpanded state, an expanded state and a second unexpanded state;
- c) mounting said balloon member on said inner shaft; and
- d) applying a torque to the inner shaft such that a torque is applied to said balloon member, said torque being applied to said inner shaft so that said inner shaft has the torque in said first unexpanded state of said expandable member.

23. The balloon catheter formed according to the method of claim 22, said balloon member having a torque in said first unexpanded state and having a torque in said second unexpanded state.

24. The balloon catheter formed according to the method of claim 23, said torque releasing during said expanded state of said balloon member.

25. The balloon catheter of claim 24 wherein the torque applied to said inner shaft remains in said expanded state of said balloon member.

26. The balloon catheter of claim 25 wherein the torque applied to said inner shaft releases when said balloon is in said second unexpanded state.

27. The balloon catheter formed according to the method of claim 22, the method further comprising the step of forming said balloon member.

28. The balloon catheter formed according to the method of claim 22, the method further comprising the step of providing an outer shaft.

29. The balloon catheter formed according to the method of claim 22, the method further comprising the step of securing the balloon at its distal end to the distal end of the inner shaft.

30. The balloon catheter formed according to the method of claim 29, the method further comprising the step of tacking the distal outer shaft to the inner shaft.
31. The balloon catheter formed according to the method of claim 22, the method further comprising the step of folding the balloon prior to applying said torque.
32. The balloon catheter formed according to the method of claim 31 wherein after folding, said balloon member has 3 or more wings.
33. A method of providing an expandable member of a balloon catheter with improved rewrap, the method comprising the steps of:
- a) providing an inner shaft having a distal end and a proximal end;
 - b) providing a balloon member having a distal end and a proximal end and a first unexpanded state, an expanded state and a second unexpanded state;
 - c) mounting said balloon member on said inner shaft; and
 - d) applying a torque to said inner shaft resulting in application of a torque to said balloon member, said torque being applied so that said inner shaft has the torque when said balloon member is in the first unexpanded state.
35. The method of claim 33 wherein said balloon having a torque in said first unexpanded state and having a torque in said second unexpanded state.
36. The method of claim 35 wherein said torque is released from said balloon member in said expanded state.
37. The method of claim 36 wherein said torque applied to said inner shaft remains when said balloon is in said expanded state.
38. The method of claim 37 wherein said torque applied to said inner shaft releases when said balloon is in said second unexpanded state.

39. The method of claim 33 further comprising the step of providing an outer shaft having a distal end and a proximal end.
40. The method of claim 33 further comprising the step of forming said balloon member.
41. The method of claim 33 further comprising the step of securing the balloon at its distal end to the distal inner shaft.
42. The method of claim 39 further comprising the step of tacking the distal outer to the inner shaft near the proximal end of said balloon.
43. The method of claim 33 further comprising the step of folding the balloon member prior to application of said torque.
44. The method of claim 43 wherein after folding, said balloon member has 2 or more wings.
45. The method of claim 43 wherein after folding, said balloon member has 3 or more wings.
46. The method of claim 33 wherein said balloon member is rotated about the y-axis at an angle of about 30° to about 360° from the y-axis in said first unexpanded state.
47. The method of claim 33 wherein said balloon member is rotated about the y-axis at an angle of about 30° to about 90° from the y-axis in said first unexpanded state.
48. The method of claim 33 wherein said balloon member is rotated about the y-axis at an angle of about 45° from the y-axis in said first unexpanded state.
49. The method of claim 33 wherein said balloon member comprises at least one member selected from the group consisting of thermoplastic block copolymers.
50. The method of claim 33 wherein said balloon member comprises at least one member selected from the group consisting of polyolefins, polyesters, polyethers, polyimides, polyamides, polyphenylene sulfides, polyphenylene oxides, polycarbonates, silicones, styrenic polymers, copolymers thereof and mixtures thereof.

51. The method of claim 33 further comprising the step of disposing a stent about the balloon member.

52. An expandable medical balloon, the expandable medical balloon comprising a proximal waist portion, a proximal cone portion, a body, a distal cone portion and a distal waist portion, the balloon secured to an inner catheter shaft at the distal waist portion and secured to an outer shaft at the proximal waist portion, the balloon further having a first unexpanded state and a second unexpanded state, the balloon having a torque in the first unexpanded state and in the second unexpanded state.

(ix) Related Proceedings Appendix

None

(x) Evidence Appendix

None